Paper No. 31

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte JEAN-LOUIS GUERET

Appeal No. 2003-0984
Application No. 09/418,825

HEARD: October 9, 2003

Before WINTERS, LORIN and SCHEINER, Administrative Patent Judges.

SCHEINER, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the final rejection of claims 1-3, 5, 7-21, 23-26 and 28-30. Claims 22 and 27 are also pending in the application, but claim 27 has been allowed, and claim 22 is merely objected to as dependent on a rejected base claim.

Claims 1, 18 and 20 are representative of the subject matter on appeal:

1. A patch comprising:
a matrix having adhesive properties in a dry state and containing at least one active substance;
said matrix being attached via one face to a porous backing and being for application via its other face to the skin;
wherein said backing is capable of containing a liquid suitable for dissolving, at least in part, said at least one active substance;
wherein said matrix is permeable to the liquid; and
wherein said at least one active substance is not suitable for migrating through the matrix, toward the other face for application to the skin, without addition of said liquid to the patch.

18. A kit constituted by a patch as defined in claim 1, and a receptacle containing a liquid for impregnating said backing.

20. A method comprising:
supplying a patch as defined in claim 1; and
impregnating said patch with said liquid before or after applying the patch to the skin.

The references relied on by the examiner are:

Katz et al. (Katz)	5,028,435	Jul. 2, 1991
Petersen et al. (Petersen)	5,156,846	Oct. 20, 1992

Claims 1-3, 5, 7-21, 23-26 and 28-30 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Katz and Petersen.

We reverse this rejection.

DISCUSSION

The claims on appeal are directed to transdermal delivery patches and methods of using them. Each of the claims requires, at a minimum, a patch comprising a liquid permeable matrix having dry adhesive properties and containing at least one active agent unsuitable for migrating through the matrix without the addition of liquid to the patch, wherein the matrix is attached on one face to a porous backing capable of containing a liquid.

Katz describes systems (devices) and methods for rate-controlled drug delivery. The systems include transdermal patches comprising “a matrix layer having a backing” and a “means for securing the system to the skin, such as a tape or adhesive layer;” the matrix layer contains the drug and “a chemical penetration enhancer which promotes transport of the drug across [the] skin” (column 2, lines 44-55). “[A]t least a portion of either the drug or the chemical penetration enhancer (or both) will be contained within a plurality of polymeric particles dispersed within the matrix layer . . . which entrap and release the drug and/or enhancer into the matrix at a preselected rate” (column 2, lines 58-65). Katz’s “suitable backing materials will generally be thin, flexible films or fabrics

such as woven and non-woven fabrics and polymeric films, such as polyethylene, polypropylene, and silicone rubber; metal films and foils; and the like" (column 4, lines 17-21). "[I]t is the view of the examiner that the non-woven fabrics disclosed by Katz [ ] as suitable backing material can be porous." Answer, page 3.

Petersen describes "a method of delivering a drug, a drug delivery system and a drug delivery kit" (Answer, page 4). According to the examiner, "the drug delivery kit includes a first patch containing one or more [proteolytic] enzymes and a second patch containing one or more drugs," and "a typical patch . . . includes a backing, a reservoir to contain the enzyme or the drug preparations, a membrane to contain and release the contents of the reservoir and a protective strip" (id.), and Petersen "teaches that the enzyme and the drug are admixed with a liquid, such as water or ethanol" and "the reservoir can be divided into two compartments, one containing the active ingredient in a dry, stable form, and the other containing the solvent to be mixed with the active ingredient" (id.). Turning to the Petersen reference, we note that the backing is described as an "occlusion means" (column 6, lines 18-20), and may be aluminized plastic, plastic film or Bioclusive™ tape (column 6, lines 20-22).

"The PTO has the burden under section 103 to establish a prima facie case of obviousness. It can satisfy this burden only by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references." In re Fine, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988) (citations omitted). An adequate showing of motivation to combine requires "evidence that 'a skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art references for

combination in the manner claimed.'" Ecolochem, Inc. v. Southern Calif. Edison Co., 227 F.3d 1361, 1375, 56 USPQ2d 1065, 1075 (Fed. Cir. 2000)

Here, the examiner's statement of the rejection leaves a great deal to conjecture. All of the claims on appeal stand rejected as unpatentable over the combined teachings of Katz and Petersen, but it appears that the examiner believes that Katz anticipates the limitations of all of the claims with the exception of those claims drawn to methods of use or kits. According to the examiner, Katz is only "deficient in the fact[ ] that it does not include a kit and method of application in the invention" (Answer, page 4), and "[i]t would have been obvious to one having ordinary skill in the art . . . to modify the transdermal drug delivery system disclosed by Katz [ ] by including the patch and the solvent in a kit and devising a method of administration according to the teachings of Petersen . . . to prevent loss of the active substance and facilitate penetration into the skin" (Answer, page 5).

Nevertheless, appellant argues that, unlike the drug in the claimed patches, the drug in Katz's patch "is always suitable for migrating through the matrix without the addition of liquid to the patch" because the enhancer, which "dissolves the drug for transport of the drug from the patch to the skin," "is part of the patch . . . upon manufacture" (Brief, page 7). In addition, appellant argues that "Katz does not suggest that [the patch's] backing material[ ] should be porous or capable of containing a liquid suitable for dissolving an active substance, as in the patches of all of the rejected claims" (Brief, page 7).

It may or may not be that Katz's active substance is contained in the matrix in such a way that it is not suitable for migrating (unless and until it is contacted by the enhancer). We need not resolve this issue, however, because all of the claims on appeal also require a porous backing "capable of containing a liquid suitable for

dissolving . . . [the] active substance," and we agree with appellant that Katz does not suggest such a limitation. In the portion of Katz that deals with transdermal patches, Katz specifically teaches that "the backing will usually be impermeable to the drug and enhancer," and it is this "impermeability [that] inhibits the loss of the drug and enhancer and allows the user to rub the patch in order to promote release of the enhancer or drug from the polymeric particles." Katz, column 4, lines 10-21.

Moreover, the examiner has not explained how adding a solvent (which Petersen uses to dissolve the active agent) to Katz's completely self-contained transdermal patch would "prevent loss of the active substance and facilitate penetration into the skin" (Answer, page 5). The matrix of Katz's patch already contains both a drug and a "chemical penetration enhancer" which dissolves the drug and "promotes transport of the drug across [the] skin" (column 2, lines 44-55); any additional solvent or liquid would seem to be superfluous.

In this case, we agree with Appellants that the examiner has not adequately explained how the references, taken individually or in combination, would have suggested transdermal patches of the particular configuration required by the claims, much less the claimed methods and kits.

For the reasons discussed above, we reverse the rejection of claims 1-3, 5, 7-21, 23-26 and 28-30 under 35 U.S.C. § 103(a) as unpatentable over Katz and Petersen.

REVERSED

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Sherman D. Winters	)
Administrative Patent Judge	)
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	) BOARD OF PATENT
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Hubert C. Lorin	) APPEALS AND
Administrative Patent Judge	)
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